

K042581
p 1/2**510(k) Summary**

OCT 13 2004

Identification of the submitter:

Submitter: Kodon (Tianjin) Electronic & Electrical Apparatus Co., LTD
No 31, Changjiang Road, Nankai District, Tianjin, P.R. China, 300193
Telephone number: 86-22-60526082
Fax number: 86-22-60526162
Contact: Liu Yi
Date of Application: 08/25/04

Identification of the product:

Device proprietary Name: KD-575 Memory Automatic Electronic Blood Pressure Monitor
Common name: Noninvasive blood pressure measurement systems
Classification name: Noninvasive blood pressure measurement system
Class II per 21 CFR 870.1130

Marketed Devices to which equivalence is claimed:

<u>Device</u>	<u>manufacture</u>	<u>510(k) number</u>
KD-559	Kodon (Tianjin) Electronic and Electrical Apparatus Co., Ltd.	K030358

Device description:

KD-575 Fully Automatic Electronic Blood Pressure Monitor is a Non-invasive blood pressure measurement system for only one person each time. Based on oscillometric and silicon integrate pressure sensor technology, this device is used to monitor systolic, diastolic blood pressure and pulse rate which will be shown on a LCD with an electronic interface module. Swathing the air cuff around the left upper arm 1-2cm above elbow joint automatically inflated and released by an internal pump, the device can analyze the signals promptly and display the results. It can storage and show 120 times measuring result with the month, day, time of measuring.

Intended use:

KD-575 Memory Automatic Electronic Blood Pressure Monitor is intended for use by medical professionals or at home to monitor and display diastolic, systolic blood pressure and pulse rate on anyone each time, except infants and unconscious people, with the air cuff around the left upper arm according to the instruction in the user's guide manual.

Comparison of technological characteristics of new device to predicate devices:

KD-575 Memory Automatic Electronic Blood Pressure Monitor can storage and show 120 times measuring results with the month, day, time of measuring. It can help patients to memorize the measuring data of their measuring results. Therefore the patients can analyze the measuring data and inspect their physical conditions. The time and the date are the advantages of KD-575 compare with the predicate device.

Clinical Tests:

Clinical tests were performed and complied the accuracy requirements of ANSI/AAMISP10-1992. The results meet or exceed the accuracy requirements of ANSI/AAMISP10-1992.

Non-clinical Tests:

All non-clinical tests coincide the following standards, including Electromagnetic Compatibility test.

IEC601-1 (1988)

Medical electrical equipment----Part 1:General requirements for safety

IEC601-1 (1988)

Amendment 2

IEC 60602-2-30: 1995

Medical electrical equipment-part2: Particular requirements for the safety of automatic cycling indirect blood pressure monitoring equipment.

GB9706.1-1995

ISO 1833-1977



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 13 2004

Ya Horng Electronic Co., Ltd.
c/o Dr Ke-Min Jen
Roc Chinese-European Industrial Research Society
No. 58, Fu-Chiun St.
Hsin-Chu City, TAIWAN 300
CHINA

Re: K042581

Trade Name: YA HORNG Automatic Digital Wrist Blood Pressure Monitor, AK-3000T
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: September 18, 2004
Received: September 22, 2004

Dear Dr. Jen:

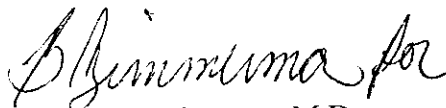
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman" followed by a stylized flourish.

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

YAHORNG

Ya Horng CO., LTD.

No. 35, Zsha Lun, Jon Zsha village,

Antin Shiang, Tainan, Taiwan, ROC

Tel: 886-6-5932201 Fax: 886-6-5935870

E-mail: lab@yahorng.com http:// www.yahorng.com

Applicant: YA HORNG CO., LTD.

510(k) Number (if known): K042581

Device Name: YA HORNG Automatic Digital Wrist Blood Pressure Monitor,
AK-3000T

● *Indications for use:*

The YA HORNG Automatic Digital Wrist Blood Pressure Monitor, Model AK-3000T, is a noninvasive blood pressure measurement system intended to measure the systolic and diastolic blood pressures and pulse rate of an adult individual, over age 18, at home by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. The cuff circumference is limited to be 5.3" – 8.5".

● *Note:*

Data Transmission: Connection to PC using RS232 cable.

Prescription Use _____

AND/OR

Over-The-Counter Use ✓

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K042581